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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/457 765

Applicant(s)

MOODY ET AL

Examiner

Michael V. Meller

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 March 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other _____

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-10 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 continues to be confusing since this is a process of producing ampicillin and applicant has defined it as a process for producing ampicillin by using 6-APA, a phenylglycine derivative and ampicillin. The process very clearly in the examples of the instant application is a process where 6-APA is reacted with a phenyl glycine derivative such as PGA to produce ampicillin. The way applicant has written the claim is confusing since applicant has chosen to define the amount of 6-APA used in terms of its relationship to ampicillin which is not understood. It would be much clearer if applicant simply recited a range of 6-APA which can be reacted with a given range of PGA to produce a given range of ampicillin. The way applicant has defined this very simple reaction is totally confusing and it does not need to be so. Further, it is interesting how applicant comments on the art of record as not specifically defining what components

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and how much of those components are used in their reactions, yet wants to claim their reaction in such a convoluted way. The present process in these claims is not defined in clear, positive and concrete steps as to enable one skilled in the art to understand what applicant is claiming. Thus, correction is required.

The term "maximum conversion" is still confusing. The examiner tuned to page 2, lines 19-29 of WO 96/02663 and still does not know what applicant is referring to ? In any event , it really would be much clearer if applicant simply inserted the pH and temperature range that would satisfy the "maximum conversion" range that applicant appears to be referring to.

Claim Rejections - 35 USC § 102

Claim Rejections - 35 USC § 103

Claims 1-10 stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 92/01061 ('061), WO 95/03420 ('420) or WO 96/02663 ('663).

First, applicant argues that '061 does not teach the concentration of 6-APA in the reaction mixture and does not disclose ratios of acylating agent to 6-APA. It is noted that in Example 1 of '061, it is clear that they are using 100 mM of 6-APA. Further, the ratio of acylating agent to 6-APA can be calculated if applicant turns to page 5 of '061

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which very clearly teaches that the amino beta-lactam (such as 6-APA) can be employed in a range of from about 50 to 750 and the acylating agent can be employed in above about 450 mM. This ratio if one figures it out, clearly encompasses applicant's claimed ratio of less than 2.5. For example, if one were to use 451 mM of phenylglycine derivative divided by 400 mM of 6-APA then the ratio would be 1.13 which would be less than 2.5 and less than 2.0 as claimed in claim 4. Fact is, the results of this patent are better than what applicant has envisioned.

Second, applicant attempts to argue that '420 teaches the recovery of phenylglycine derivative amide from a mixture obtained after an enzymatic preparation of a beta-lactam antibiotic. Fact is, the patent discloses and claims a process for the preparation of a beta-lactam derivative, namely ampicillin. Thus, it applicant's comments are not understood.

Third, applicant argues that '663 teaches a continuous process for preparation of ampicillin by enzymatic acylation. They state that the process is carried out as a continuous process at a constantly high concentration of the reactants. They then state that there is no suggestion that the process can be modified to a batch process and that there is no suggestion that the process can be carried out employing specific concentrations of the present invention.

Fact is, according to example 1 of '663, they use 200 mM D-HPGM (a phenylglycine derivative) and 200 mM 6-APA which would result in a ratio of 1.0. To modify the process to a batch reaction would have been obvious since batch reactions

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

MVM
May 31, 2001

[Handwritten signature]
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